| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,690 | KODAMA ET AL. | |
| | Examiner | Art Unit | |
| | Michael C. Wilson | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,11,12 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *11,12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *9-24-08* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10-4-07,11-9-07,5-16-08,9-29-08.

## DETAILED ACTION

Claims 1-15 are pending and under consideration.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 12, 14 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claim 1 is directed toward a transgenic mouse whose genome comprises a nucleic acid sequence encoding baculovirus gp64, wherein the gp64 is soluble and lacks a tansmembrane region and wherein the mouse is fertile. Claim 11 is drawn to a method making antibodies by immunizing the transgenic mouse of claim 1 with an immunogen comprising a target antigen, and obtaining an antibody against the target antigen or a gene encoding such an antibody.

The specification teaches making transgenic mice expressing the extracellular, soluble region of baculovirus gp64 (SEQ ID NO: 3) (pg 16, lines 18-20; pg 17, lines 14-33). The specification states mice were immunized with a budding baculovirus (pepT1-AcMNPV (pepT1-VB)) (sentence bridging pg 19-20), and then states mice were given 1 mg/animal (pg 20, lines 2-7). The specification goes on to state mice expressing soluble gp64 induced tolerance (pg 20, lines 17-19; Fig. 3); however, Fig 3 merely shows expression of soluble gp64.

Since the time of filing, Saitoh (J. Immunological Methods, 2007, Vol. 332, pg 104-117) teaches PepT1 must be expressed on the surface of baculoviral particles

which is not readily apparent from the teachings in the specification and is considered essential to the invention.

The specification provides no guidance how to use the mouse claimed to isolate genes encoding antibodies; the phrase "or a gene encoding such an antibody" should be deleted.

The specification does not teach how to use the method to induce antibodies against any target antigen. The specification fails to teach that the target antigen must be a membrane protein that is not from baculovirus and that it must be displayed on the surface of a baculovirus administered to the gp64 transgenic mouse. More specifically:

Claim 12 is limited to an immunogen comprising a target antigen, wherein the immunogen is baculovirus. Claim 14 is limited to a membrane protein "target antigen." However, the phrase "target antigen" in claim 1 encompasses gp64 baculovirus antigen, which is not a useful target antigen in the method claimed because the specification states the mice are tolerized to gp64. The phrase "target antigen" in claim 1 also encompasses proteins that are not expressed by baculovirus and proteins that are not displayed on the surface of the baculoviral particle. However, it appears from Saitoh that the target antigen must be displayed on the surface of baculoviral particles for antibody production to occur, which is considered essential to the invention. If the target antigen is not expressed in context of baculovirus, then using the transgenic of claim 1 is moot because the method can be performed with a wild-type mouse. If the target antigen is expressed inside the baculoviral particle but not displayed on the

surface, the antigen would not induce an antibody response because the humoral immune system (for antibody production) would not have access to a target antigen.

Looking the examples, applicants do not clearly set forth the structure of what was administered to the mice. Baculovirus is not administered at 1 mg/animal, for example (pg 20, line 7); viral doses are measured in particle numbers or infectious units, not milligrams. The structure of pepT1-AcMNPV used to immunize the mice is wholly unclear. While the specification cites Fig. 3 and states mice expressing soluble gp64 induced tolerance (pg 20, lines 17-19), Fig 3 merely shows expression of soluble gp64. Accordingly, applicants' conclusion based on Fig. 3 is flawed. Most importantly, applicants do not obtain antibodies against pepT1. Accordingly, the specification is missing essential information for those of skill to use the mice of claim 1 to induce an antibody as claimed. As such, the specification fails to teach those of skill how to use the method claimed.

It is noted that support for a target protein that is a membrane protein is in claim 14. Support for a baculovirus comprising a target antigen is in claim 12. However, support for displaying the membrane protein on the surface of the baculoviral particle and for using a target antigen that is non-baculoviral (specifically not gp64) cannot be found.

Upon overcoming the above rejections, the claims would be limited to: a method for producing an antibody against a target antigen comprising:

(a) preparing a baculoviral particle comprising a nucleic acid sequence encoding a non-baculovirus membrane protein, wherein the non-baculoviral membrane protein is displayed on the surface of the baculoviral particle;

(b) immunizing the transgenic mouse of claim 1 with the baculoviral particle;

(c) recovering an antibody that recognizes the non-baculoviral membrane protein from the transgenic mouse.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/516603. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both require making antibodies against a target antigen using a transgenic mouse expressing gp64 that is immunotolerant to gp64. The species of pepT1 in '603 is obvious in view of the disclosure of '690. The species of membrane protein and baculovirus in claims 12 and 14 of '690 are obvious in view of the disclosure of '603. The genus of mouse expressing gp64 in '603 anticipates the species of mouse expressing soluble '690 (one-way obviousness). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Tsuchiya (Jan. 21, 2003, therapeutic antibody presentation, pg 1-21)

Mancini (1993, J. Med. Virol., Vol. 39, pg 67-74)

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner